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09/691,957	10/18/2000	Samuel Benjamin Schaevitz	ACBI.049.00US	5382

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ACLARA BIOSCIENCES, INC.  
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EXAMINER

QUAN, ELIZABETH S

ART UNIT PAPER NUMBER

1743

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/691,957

Applicant(s)

SCHAEVITZ ET AL.

Examiner

Elizabeth Quan

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.

- 4) ☒ Interview Summary (PTO-413) Paper No(s). 04052004
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 2-5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,273,718 to Skold et al. in view of U.S. Patent No. 6,251,343 to Dubrow et al.

Referring to claims 3-5, Skold et al. shows a substrate (35) of planar surface with openings surrounded by a collar (see FIGS 2-4). Skold et al. do not disclose the materials used in the apparatus. Dubrow et al. discloses the substrate and cover layer injection molded polymeric or plastic part from a variety of materials including an acrylic polymer such as polymethylmethacrylate (PMMA) (see COL. 3, lines 61-67; COL. 4, lines 1-7; COL. 8, lines 66 and 67; COL. 9, lines 1-12). To provide an effective barrier between neighboring reservoirs the upper surface of the cover layer may be coated with a polymer (see COL. 7, lines 62-67; COL. 8, lines 1-3). The cover layer may be attached to the body structure of the device by adhesive bonding, preferably using U.V. curable adhesives for tight sealing against evaporation (see COL. 9, lines 13-24). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Skold et al. to provide a plastic molded microfluidic device including a conformable lid with adhesive coating to provide an effective barrier between reservoirs and better sealing between the cover plate and body structure to prevent evaporation.

Referring to claims 2 and 15, Skold et al. in view of Dubrow et al. do not disclose the thickness of the collar. According to In re Aller, the discovery of an optimum or workable range of collar thickness is characterized as routine experimentation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the thickness of the collar as necessary to prevent contamination between wells and increase the effective volume of the wells. Therefore, the claimed device is not patentably distinct from prior art device based on the thickness of the collar.

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5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,273,718 to Skold et al.

Referring to claim 6, Skold et al. shows a substrate (35) of planar surface with openings surrounded by a collar (see FIGS 2-4). Skold et al. do not disclose the volumes of the reservoirs and the height and thickness of the collars. Applying the decision made by the Federal Circuit in *Gardner v. TEC Systems, Inc.*, the volume of the reservoirs would not affect the performance of the claimed device respective to prior art device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the volume of the reservoirs as necessary to process the desired volume of samples. Furthermore, according to *In re Aller*, the discovery of an optimum or workable range is characterized as routine experimentation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the height and thickness of the collar as necessary to prevent contamination between wells and increase the effective volume of the reservoirs. Therefore, the claimed device is not patentably distinct from prior art device based on the height and thickness of the collar as well as the volume of the reservoir.

6. Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,273,718 to Skold et al. as applied to claim 6, and in further view of U.S. Patent No. 6,251,343 to Dubrow et al.

Referring to claim 7, Skold et al. do not disclose channels. Dubrow et al. discloses ports in the body structure, which are in fluid communication with one or more channels in the first channel network (see FIGS. 2A-2F and 3B; ABSTRACT). While

Dubrow et al. do not explicitly state why the reservoirs are in communication through a channel, it appears the applied pressure and voltage gradients are better dispersed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate reservoirs in communication with channels of Dubrow et al. to the apparatus of Skold et al. for better dispersion of applied pressure and voltage gradients.

Referring to claims 8-11, Skold et al. do not disclose the materials used in the apparatus. Dubrow et al. discloses the substrate and cover layer injection molded polymeric or plastic part from a variety of materials including an acrylic polymer such as polymethylmethacrylate (PMMA) (see COL. 3, lines 61-67; COL. 4, lines 1-7; COL. 8, lines 66 and 67; COL. 9, lines 1-12). To provide an effective barrier between neighboring reservoirs the upper surface of the cover layer may be coated with a polymer (see COL. 7, lines 62-67; COL. 8, lines 1-3). The cover layer may be attached to the body structure of the device by adhesive bonding, preferably using U.V. curable adhesives for tight sealing against evaporation (see COL. 9, lines 13-24). A flexible gasket may optionally be placed between the upper surface of the body structure and lower surface of the cover layer (see COL. 9, lines 26-29). Additionally, the reservoirs spaced according to conventional multi-well plates, such as a 96-well, 384-well, or 1536-well (see COL. 9, lines 53-59). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Skold et al. to provide a plastic molded microfluidic device including a conformable lid with adhesive coating to provide an effective barrier between reservoirs and better sealing

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between the cover plate and body structure to prevent evaporation and position reservoirs to conveniently match existing multi-well plates.

7. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,273,718 to Skold et al. in view of U.S. Patent No. 6,251,343 to Dubrow et al.

Referring to claims 12-14, Skold et al. do not disclose a compliant lid or an electrokinetic device. Fluid volumes are introduced into the ports (see COL. 7, lines 15-23). Dubrow et al. discloses the substrate and cover layer injection molded polymeric or plastic part from a variety of materials including an acrylic polymer such as polymethylmethacrylate (PMMA) (see COL. 3, lines 61-67; COL. 4, lines 1-7; COL. 8, lines 66 and 67; COL. 9, lines 1-12). To provide an effective barrier between neighboring reservoirs the upper surface of the cover layer may be coated with a polymer (see COL. 7, lines 62-67; COL. 8, lines 1-3). The cover layer may be attached to the body structure of the device by adhesive bonding, preferably using U.V. curable adhesives for tight sealing against evaporation (see COL. 9, lines 13-24). A flexible gasket may optionally be placed between the upper surface of the body structure and lower surface of the cover layer (see COL. 9, lines 26-29). Further, the microfluidic device uses an electrokinetic material transport system, which create virtual valves including no mechanical or moving parts, to direct and transport materials through the channels of the device (see COL. 4, lines 56-59; COL. 6, lines 22-24). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a compliant/adhesive lid with a gasket for effective sealing against

evaporation and make use of an electrokinetic material transport system to induce virtual valves with no mechanical or moving parts to the apparatus of Skold et al.

***Response to Arguments***

8. Examiner appreciates the amendment and response the Applicant has provided.

However, the amendment has raised new issues.

9. Applicant's arguments filed 7/30/2002 have been fully considered but they are not persuasive.

Applicant argues that Skold et al. fail to teach a microfluidic device with a planar substrate having at least one microstructure with an opening in the surface and at least a portion of the openings being surrounded by a collar in relief. Applicant has not provided structural limitations of a microfluidic device and associated microstructures nor does the specification define a microfluidic device and associated microstructures. The limitations in the claim read on a standard microtiter plate with wells. Skold et al. provide microstructures with an opening in the surface that are surrounded by a collar in relief as evident by the portions extending from the sidewalls of the microstructures and the ridges in between the collars (see FIGS. 3 and 4).

Applicant argues that the device of Skold et al. has a gas pressure device with a planar plate and inflatable collar positioned on the sides of the plate not a collar in relief positioned around the microstructure opening. Examiner refer Applicant to FIGS. 3 and 4. The ridges in between the microstructures with openings define the raised collars extending from the sidewalls of the microstructure and the ridges.



Applicant argues that Skold et al. fail to teach covering the collar with a lid of a conformable material or an adhesive coating. Examiner indicates that Dubrow et al. was used in combination with Skold et al. to provide motivation for the limitation.

Applicant argues that Dubrow et al. in combination with Skold et al. do not make up for the deficiencies in Skold et al. Applicant argues that Dubrow et al. is not concerned with sealing the microfluidic device. Applicant argues that Dubrow et al. teach a ridge surrounding the apertures of the cover layer to prevent spill over as well as to isolate the apertures electrically and spatially. Examiner indicates that Applicant has not claimed sealing. The lid simply covers the collars. The cover layer of Dubrow et al. functions as a cover by preventing cross talk or spill over. It is well known in the art to provide an aperture in the cover to access the contents of the microstructure. Furthermore, some experiments do not require sealing from the environment.

Applicant has argued that the prior art of record does not deal with a microfluidic device. While Applicant has not claimed a microfluidic device, U.S. Patent No. 6,251,343 to Dubrow et al. can be interpreted in another light to involve a microfluidic device. Dubrow et al. disclose a microfluidic device (300) comprising a substrate (200) with a planar surface with at least one microstructure (206) formed thereon (see FIGS. 2 and 3; COL. 11, lines 4-7). The microstructures are spaced according to conventional multi-well plates, such as a 96-well, 384-well, or 1536-well (see COL. 9, lines 53-59). The substrate (200) is an injection molded polymeric or plastic part from a variety of materials including an acrylic polymer such as polymethylmethacrylate (PMMA) (see COL. 3, lines 61-67; COL. 4, lines 1-7; COL. 8, lines 66 and 67; COL. 9, lines 1-12).

There is a plurality of openings (206) in the surface of the microstructures, and at least a portion of the openings (206) is surrounded by a collar in relief as defined by a ridge (208) (see FIGS. 2 and 3; COL. 9, lines 40-67; COL. 10, lines 1-4). The ports in the body structure are in fluid communication with one or more channels in the first channel network (see FIGS. 2A-2F and 3B; ABSTRACT). The microfluidic device uses an electrokinetic material transport system, which create virtual valves including no mechanical or moving parts, to direct and transport materials through the channels of the device (see COL. 4, lines 56-59; COL. 6, lines 22-24).

### *Conclusion*

**10.** The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art includes one or more limitations in the claims.

Note U.S. Patent No. 5,961,926 to Kolb et al. Kolb et al. disclose a device comprising a substrate (18) with a planar surface (see FIGS. 1-3). The planar surface has at least one microstructure (48) formed thereon (see FIGS. 1-3). The microstructures are positioned in accordance with a 96 microtiter well format (see FIGS. 1-3). It appears that the microstructures (48) are connected to one another by microchannels in shield (56) such that liquid may collect in tray (14) (see FIG. 2). There is a plurality of openings in the surface of the microstructures (48), and each of the openings is surrounded by a collar in relief (49) (see FIGS. 1-3; COL. 5, lines 25-42). The collar has a height of 0.015 inches or 0.381 millimeters (see COL. 5, lines 17-19). The collar is covered with a lid (20) of a conformable film with an adhesive coating (see FIGS. 1-3; COL. 7, lines 27-32; COL. 8, lines 13 and 14). In using the device, small volumes of MICROSCINT-O

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lipophilic scintillation cocktail and nuclide samples may be introduced into the device, and a compliant or adhesive lid (20) may be applied to each of the collars (40) (see COL. 6, lines 55-67; COL. 7, lines 1-37, 66, and 67; COL. 8, lines 1-14). Ten to thirty-five microliters per microstructure (48) is preferred (see COL. 7, lines 25-27).

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 879-9310 for regular communications and (703) 872-9311 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan  
Examiner  
Art Unit 1743

eq  
April 5, 2004

  
ARLEN SODERQUIST  
PRIMARY EXAMINER